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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,429	06/24/2003	Zifei Wang	A03P1031	4308

36802 7590 10/16/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,429	WANG ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060721*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 13, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al. (US 6,381,493, hereinafter "Stadler").

3. In regards to claim 1 and 18, Stadler et al. disclose an implantable medical device comprising receiving electrical signals from the heart with a sensing circuit, identifying segments of the cardiac signal subsequent to ventricular repolarization (Fig. 5; please note that these points are part of the T-wave, thus subsequent to repolarization, based on the interpretation above), and detects ischemia based on an examination of the segments (Fig. 6, element 6). Please see the cited Verrier (US 5,148,812) reference for evidence that the T-wave comprises the ST segment (col. 1, line 56) and that voltage (potential energy) is an energy value.

4. In regards to claim 2, Stadler et al. disclose that ischemia is detected to predict myocardial infarction (col. 1, line 45).

5. In regards to claims 13, 15, and 17, a warning signal is provided to an external device to indicate ischemia (Fig. 1A and col. 8, line 55).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler. Stadler discloses the essential features of the claimed invention except for a warning comprising a subcutaneous electrical notification signal. Subcutaneous "tickle" warnings are well known in the implantable device art to provide a notification signal to a patient with a totally implanted system. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Stadler's invention by providing a "tickle" warning to provide a notification signal to a patient with a totally implanted system.

9. Claims 3, 4, 7, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler in view of Lerner (US 5,213,106, hereinafter "Lerner"). Stadler discloses the essential features of the claimed invention, including the following:

10. In regards to claims 4, 16, 19 and 20, Stadler discloses utilizing a high-pass filtered signal (col. 25, line 41), deriving an energy value (potential energy) following each ventricular repolarization with a running average (col. 26, line 3), inputting a first and second threshold value (col. 26, line 35), and detecting a sharp falling edge based on the average value, running average and thresholds (col. 26, line 15). Please note that the examiner interprets a band-pass filter as a high-pass and low-pass filter. Stadler does not disclose that the energy value is a total amount of energy in each segment or detecting a sharp falling edge. Lerner teaches of determining ischemia based on total energy values and a sharp falling edge ("deeply negative") to accurately detect ischemia based on ECG data (col. 5, line 42). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Stadler's invention by determining ischemia based on total energy values and a sharp falling edge to accurately detect ischemia based on ECG data.

11. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler in view of Lerner, as applied to claim 4 above, and further in view of Berger (US 5,560,368, hereinafter "Berger"). Stadler's modified invention discloses the essential features of the claimed invention except for a high-pass filter with a frequency in the range 0.1 to 5.0 Hz or at least 1.0 Hz. Berger teaches of a method of measuring ECG intervals using a filter with a high-pass cutoff frequency of about 1 Hz (col. 10, line 48)

to preserve the repolarization signal. Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to provide a cutoff frequency of 1 Hz to Stadler's modified invention to preserve the repolarization signal.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler in view of Lerner, as applied to claim 7 above, and further in view of Fischell et al. (US 6,609,023, hereinafter "Fischell"). Stadler's modified invention discloses the essential features of the claimed invention except for defining a start time of S1 + S_to_S_Interval / 4 and an end time of S2 - S_to_S_Interval / 4. Fischell teaches of defining the ST interval based on R-R intervals to ensure that an accurate T-wave signal is acquired, regardless of heart rate (col. 21, line 41). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to define a start time of S1 + S_to_S_Interval / 4 and an end time of S2 - S_to_S_Interval / 4 for Stadler's invention to detect the T-wave from the easily recognizable R-wave. Furthermore, it is well known in the art to acquire desired features based on the R-wave or R-R intervals due to the ease of recognition of the R-wave.

13. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler in view of Lerner, as applied to claim 7 above, and further in view of Park et al. (US 2003/0153956, hereinafter "Park"). Stadler's modified invention discloses the essential features of the claimed invention except for deriving a running average using the equation as claimed. Park teaches of a digital smoothing method using the claimed equation to provide a less noisy signal that can be filtered using bit-shifting instead of arithmetic (par. 0083). Therefore, it would have been obvious to one having ordinary

skill in the art at the time of invention to further modify Stadler's invention by deriving a running average using the equation as claimed to provide a less noisy signal that can be filtered using bit-shifting instead of arithmetic.

14. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler in view of Lerner, as applied to claim 4 above, and further in view of Beker et al. (US 2003/0208129, hereinafter "Beker"). Stadler's modified invention discloses the essential features of the claimed invention except for determining whether the energy integral minus the running average exceeds the first threshold or the running average exceeds the second threshold and determining whether this value is below both thresholds. Beker teaches of a method of signal analysis for ECG signals comprising comparing a current wave with a reference wave (fig. 7, element 116), comparing averaged waves to a threshold (fig. 7, element 124), taking action if both thresholds are exceeded (fig. 7, element 126) and ending if neither threshold is exceeded (fig. 7) to ensure that both individual measurements and average measurements can induce the active state. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Stadler's invention by determining whether the energy integral minus the running average exceeds the first threshold or the running average exceeds the second threshold and determine whether this value is below both thresholds to ensure that both individual measurements and average measurements can induce the active state.

Response to Arguments

15. Applicant's arguments, see "Remarks", filed 7/21/2006, with respect to the claim rejections under 35 USC 112 have been fully considered and are persuasive. The rejection of claims 1-20 under 35 USC 112(1) and 112(2) have been withdrawn.

16. Applicant's arguments filed 7/21/2006 with respect to the art rejections have been fully considered but they are not persuasive. Although the plain language of the independent claims recite cardiac signal portions "subsequent to a ventricular repolarization and prior to the ventricular depolarization following the ventricular repolarization", Applicant provides a definition in "Remarks" of 4/4/2006 that "Depending on the integers used, it is possible that a portion of a T-wave may be included in the segment and thus included in the energy calculation. It, however, is not required that some energy of a T-wave be used to detect ischemia." Additionally, claim 8 recites an embodiment wherein a portion of the T-wave would potentially be part of the interval in question. So although the plain language of the independent claims specify "subsequent to a ventricular repolarization and prior to the ventricular depolarization following the ventricular repolarization", the definition provided by Applicant in "Remarks" of 4/4/2006 and claim 8 indicate that some portion of the T-wave *may* be present in the energy calculation. As such, the "special definition" supersedes the plain language of the claim and the interpretation that the energy calculation may include the T-wave will be applied.

17. Further, Applicant argued that the statement that "[d]epending on the integers used, it is possible that a portion of a T-wave may be included in the segment and thus

included in the energy calculation" applies to one having less than ordinary skill in the art, thus inclusion of a portion of the T-wave should be disqualified. This is not found moving because there was no mention of an artisan with less than ordinary skill in the remarks of 4/4/2006. Therefore, Examiner must maintain the assertion that the energy calculation may contain T-wave energy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
10/12/06

GEORGE R. EVANISKO
PRIMARY EXAMINER
10/12/6